

REMARKS/ARGUMENTS

The Office Action mailed March 6, 2007 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims presented for examination are: claims 1-56.

Double Patenting

On page 2 of the March 6, 2007 Office Action, claims (1, 2) 3, 4, 5, 8, 45, and 46 were provisionally rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims (1), 4, 10, 11, 18, 19, and 23 of Co-pending Application 10/781,582.

Applicants have amended claims (1, 2) 3, 4, 5, 8, 45, and 46 and believe the invention claimed in amended claims (1, 2) 3, 4, 5, 8, 45, and 46 is patentably distinct over claims (1), 4, 10, 11, 18, 19, and 23 of Co-pending Application 10/781,582.

Applicants believe they have provided a full and complete response to the obviousness-type double patenting rejection in the Office Action mailed March 6, 2007.

35 USC §102(b) Rejection - Maitland et al Reference

In the Office Action mailed March 6, 2007, claims 1, 2, 5-7, 12-15, 21, 23, 24, 27-29, 34-37, and 43 were rejected under 35 U.S.C. §102(b) as being anticipated by the Maitland et al reference (US Published Patent Application No. 2002/0095169).

The standard for a 35 U.S.C. §102 rejection is stated in RCA Corp. v. Applied Digital Systems, Inc, 221PQ 385, 388 (d. Cir. 1984) "Anticipation is established only when a single prior art reference discloses, either expressly or

under principles of inherency, each and every element of a claimed invention.” Applicants have amended claims 1, 2, 5-7, 12-15, 21, 23, 24, 27-29, 34-37, and 43 and believe the invention claimed in amended claims 1, 2, 5-7, 12-15, 21, 23, 24, 27-29, 34-37, and 43 is not anticipated by the Maitland et al reference. Applicants point out that the many elements of Applicants’ amended claims 1, 2, 5-7, 12-15, 21, 23, 24, 27-29, 34-37, and 43 are not found in the Maitland et al reference. For example the following elements of Applicants’ amended independent claims, (claims 1, 23, and 45) are not found in the Maitland et al reference:

Claim 1

“a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam,” or

“a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

“a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly.”

Claim 23

“shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam,” or

“a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism,” or

“an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in interior of the aneurism.”

Claim 45

“providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in

the interior of the physical anomaly and a larger primary shape for occluding the anomaly,” or

“positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape,” or

“causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly.”

Since the many elements of Applicants’ amended claims 1, 2, 5-7, 12-15, 21, 23, 24, 27-29, 34-37, and 43; particularly the elements described above; are not found in the Maitland et al reference, the Maitland et al reference does not support a 35 U.S.C. §102(e) rejection of Applicants’ amended claims 1, 2, 5-7, 12-15, 21, 23, 24, 27-29, 34-37, and 43 and the rejection should be withdrawn.

35 U.S.C. §102(b) Rejection - Kamiya et al Reference

In the Office Action mailed March 6, 2007, claims 1, 2, 5-7, 21, 23, 24, 27-29, 43, 45, and 47 were rejected under 35 U.S.C. §102(b) as being anticipated by the Kamiya et al reference (US Patent No. 5,192,301).

The standard for a 35 U.S.C. §102 rejection is stated in RCA Corp. v. Applied Digital Systems, Inc., 221PQ 385, 388 (d. Cir. 1984) “Anticipation is established only when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention.” Applicants have amended claims 1, 2, 5-7, 21, 23, 24, 27-29, 43, 45, and 47 and believe the invention claimed in amended claims 1, 2, 5-7, 21, 23, 24, 27-29, 43, 45, and 47 is not anticipated by the Kamiya et al reference. Applicants point out that the many elements of Applicants’ amended claims 1, 2, 5-7, 21, 23, 24, 27-29, 43, 45, and 47 are not found in the Kamiya et al reference. For example, the following

elements of Applicants' amended independent claims, (claims 1, 23, and 45) are not found in the Kamiya et al reference:

Claim 1

"a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam," or

"a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly," or

"a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly."

Claim 23

"shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam," or

"a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism," or

"an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in interior of the aneurism."

Claim 45

"providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

"positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape," or

“causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly.”

Since the elements described above are not found in the Kamiya et al reference, the Kamiya et al reference does not support a 35 U.S.C. §102(e) rejection of Applicants’ amended claims 1, 2, 5-7, 21, 23, 24, 27-29, 43, 45, and 47 and the rejection should be withdrawn.

35 U.S.C. §103(a) Rejection - Kamiya et al In View of Bleys et al

In the Office Action mailed March 6, 2007, claims 3, 22, 25, and 44 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Kamiya et al reference in view of the Bleys et al reference (US Patent No. 6,034,149).

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 3, 22, 25, and 44 under 35 U.S.C. §103(a) over the Kamiya et al reference in view of the Bleys et al reference is respectfully traversed. Applicants have amended claims 3, 22, 25, and 44 and submit that the Kamiya et al reference and the Bleys et al reference do not support a 35 U.S.C. §103(a) rejection. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int’l. Co. v. Teleflex, Inc.). Second, there must be a reasonable expectation of success. Third, the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed.

Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in *Graham v. John Deere Co.* is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: “the scope and content of the prior art,” ascertaining “the differences between the prior art and the claims at issue,” and resolving “the level of ordinary skill in the pertinent art.”

The Criteria That The Kamiya et al and Bleys et al References Must Teach All Claim Limitations Has Not Been Established

Applicants point out that the many elements of Applicants’ amended claims 3, 22, 25, and 44 are not found in the Kamiya et al reference or the Bleys et al reference. For example, the following elements of Applicants’ claims 3, 22, 25, and 44 are not found in the Kamiya et al reference or the Bleys et al reference:

“a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam,” or

“a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

“a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly,” or

“wherein said shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent,” or

“shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam,” or

“a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism,” or

“an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in interior of the aneurism,” or

“wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent,” or

wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer foam body having a secondary shape for being positioned in the interior of the aneurism and a larger primary shape for occluding the aneurism.”

Since the limitations listed and described above are not shown by either the Kamiya et al reference or the Bleys et al reference, a *prima facie* case of obviousness has not been established. Further, since both the Kamiya et al reference and the Bleys et al reference fail to show the claim limitations of Applicants' claims 3, 22, 25, and 44, there can be no combination of the two references that would show Applicant's invention. There is no combination of Kamiya et al reference and the Bleys et al reference that would produce the combination of elements of Applicants' amended claims 3, 22, 25, and 44. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 3, 22, 25, and 44 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

The Criteria That There Must Be Reasons for Combining The Kamiya et al and Bleys et al References Has Not Been Established

The first criteria of the Examiner's initial burden of factually supporting a *prima facie* conclusion of obviousness is: the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). The rejection in the Office Action mailed March 6, 2007 does not provide an explanation of how or

why the Kamiya et al reference and the Bleys et al reference could be combined. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 3, 22, 25, and 44 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

35 U.S.C. §103(a) Rejection - Maitland et al In View of Bleys et al

In the Office Action mailed March 6, 2007, claims 3, 8-11, 22, 25, 30-33, and 44 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Maitland et al reference in view of the Bleys et al reference.

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 3, 8-11, 22, 25, 30-33, and 44 under 35 U.S.C. §103(a) over the Maitland et al reference in view of the Bleys et al reference is respectfully traversed. Applicants have amended claims 3, 8-11, 22, 25, 30-33, and 44 and submit that the Maitland et al reference and the Bleys et al reference do not support a 35 U.S.C. §103(a) rejection. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). Second, there must be a reasonable expectation of success. Third, the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in *Graham v. John Deere Co.* is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires

determining: “the scope and content of the prior art,” ascertaining “the differences between the prior art and the claims at issue,” and resolving “the level of ordinary skill in the pertinent art.”

The Criteria That The Maitland et al and Bleys et al References Must Teach All Claim Limitations Has Not Been Established

Applicants point out that the many elements of Applicants’ amended claims 3, 8-11, 22, 25, 30-33, and 44 are not found in the Maitland et al reference or the Bleys et al reference. For example, the following elements of Applicants’ claims 3, 8-11, 22, 25, 30-33, and 44 are not found in the Maitland et al reference or the Bleys et al reference:

“a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam,” or

“a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

“a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly,” or

“wherein said shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent,” or

“shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam,” or

“a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism,” or

“an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in interior of the aneurism,” or

“wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape memory polymer foam with an open cell foam structure that has an expansion ratio in the range of 200 percent to 20000 percent,” or

wherein said shape memory material body that comprises a shape memory polymer foam comprises a shape memory polymer foam body having a secondary shape for being positioned in the interior of the aneurism and a larger primary shape for occluding the aneurism.”

Since the limitations listed and described above are not shown by either the Maitland et al reference or the Bleys et al reference, a *prima facie* case of obviousness has not been established. Further, since both the Maitland et al reference and the Bleys et al reference fail to show the claim limitations of Applicants’ claims 3, 8-11, 22, 25, 30-33, and 44, there can be no combination of the two references that would show Applicant’s invention. There is no combination of Maitland et al reference and the Bleys et al reference that would produce the combination of elements of Applicants’ amended claims 3, 8-11, 22, 25, 30-33, and 44. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 3, 8-11, 22, 25, 30-33, and 44 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

The Criteria That There Must Be Reasons for Combining The Maitland et al and Bleys et al References Has Not Been Established

The first criteria of the Examiner’s initial burden of factually supporting a *prima facie* conclusion of obviousness is: the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int’l. Co. v. Teleflex, Inc.). The rejection in the Office Action mailed March 6, 2007 does not provide an explanation of how or

why the Maitland et al reference and the Bleys et al reference could be combined. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 3, 8-11, 22, 25, 30-33, and 44 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

35 U.S.C. §103(a) Rejection - Kamiya or Maitland In View of Porter

In the Office Action mailed March 6, 2007, claims 17-20 and 39-42 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Kamiya et al reference or the Maitland et al reference in view of the Porter reference (US 2002/0165582).

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 17-20 and 39-42 under 35 U.S.C. §103(a) over the Kamiya et al or Maitland et al reference in view of the Porter reference is respectfully traversed. Applicants have amended claims 17-20 and 39-42 and submit that the Kamiya et al or Maitland et al reference and the Porter reference do not support a 35 U.S.C. §103(a) rejection. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). Second, there must be a reasonable expectation of success. Third, the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in

Graham v. John Deere Co. is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: “the scope and content of the prior art,” ascertaining “the differences between the prior art and the claims at issue,” and resolving “the level of ordinary skill in the pertinent art.”

The Criteria That The Kamiya et al or Maitland et al and Porter References Must Teach All Claim Limitations Has Not Been Established

Applicants point out that the many elements of Applicants’ amended claims 17-20 and 39-42 are not found in the Kamiya et al or Maitland et al reference or the Porter reference. For example, the following elements of Applicants’ claims 17-20 and 39-42 are not found in the Kamiya et al or Maitland et al reference or the Porter reference:

“a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam,” or

“a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly,” or

“a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly,” or

“wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles that convert RF radiation to heat,” or

“wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles of a material which can selectively absorb RF radiation converting it to heat,” or

“wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and

a secondary shape comprises nanoparticles that convert RF radiation to heat," or

"wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises nanoparticles of a material which can selectively absorb RF radiation converting it to heat," or

"shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam," or

"a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism," or

"an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in interior of the aneurism," or

"wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles that convert RF radiation to heat," or

"wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises microparticles of a material which can selectively absorb RF radiation converting it to heat," or

"wherein said activation system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises nanoparticles that convert RF radiation to heat," or

"wherein said activation system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises nanoparticles of a material which can selectively absorb RF radiation converting it to heat."

Since the limitations listed and described above are not shown by the Kamiya et al reference or the Maitland et al reference or the Porter reference, a *prima facie* case of obviousness has not been established. Further, since the Kamiya et al reference, the Maitland et al reference, and the Porter reference fail to show the claim limitations of Applicants' claims 17-20 and 39-42, there can be no combination of the three references that would show Applicant's invention. There is no combination of Kamiya et al reference and the Maitland et al reference and the Porter reference that would produce the combination of elements of Applicants' amended claims 17-20 and 39-42. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 17-20 and 39-42 under 35 USC §103(a), and the rejection should be withdrawn.

The Criteria That There Must Be Reasons for Combining The Kamiya et al and the Maitland et al and the Porter References Has Not Been Established

The first criteria of the Examiner's initial burden of factually supporting a *prima facie* conclusion of obviousness is: the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). The rejection in the Office Action mailed March 6, 2007 does not provide an explanation of how or why the Kamiya et al reference and the Maitland et al reference could be combined. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 17-20 and 39-42 under 35 USC 103(a), and the rejection should be withdrawn.

35 USC §103(a) Rejection – Claims 46 & 49 Kamiya In View of Bleys

In the Office Action mailed March 6, 2007, claims 46 and 49 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Kamiya et al reference in view of the Bleys et al reference (US Patent No. 6,034,149).

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 46 and 49 under 35 U.S.C. §103(a) over the Kamiya et al reference in view of the Bleys et al reference is respectfully traversed. Applicants have amended claims 46 and 49 and submit that the Kamiya et al reference and the Bleys et al reference do not support a 35 U.S.C. §103(a) rejection. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). Second, there must be a reasonable expectation of success. Third, the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in *Graham v. John Deere Co.* is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: "the scope and content of the prior art," ascertaining "the differences between the prior art and the claims at issue," and resolving "the level of ordinary skill in the pertinent art."

The Criteria That The Kamiya et al and Bleys et al References Must Teach All Claim Limitations Has Not Been Established

Applicants point out that the many elements of Applicants' amended claims 46 and 49 are not found in the Kamiya et al reference or the Bleys et al

reference. For example, the following elements of Applicants' claims 46 and 49 are not found in the Kamiya et al reference or the Bleys et al reference:

"providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

"positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape," or

"causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly," or

"wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises providing a shape memory polymer foam body with an open cell foam structure that has pores and wherein said pores have a mean pore size between ten microns and fifty microns with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

"wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using a collapsed shape memory polymer foam device connected at the end of a guide wire."

Since the limitations listed and described above are not shown by either the Kamiya et al reference or the Bleys et al reference, a *prima facie* case of obviousness has not been established. Further, since both the Kamiya et al reference and the Bleys et al reference fail to show the claim limitations of Applicants' claims 46 and 49, there can be no combination of the two references that would show Applicant's invention. There is no combination of Kamiya et al

reference and the Bleys et al reference that would produce the combination of elements of Applicants' amended claims 46 and 49. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 46 and 49 under 35 USC §103(a), and the rejection should be withdrawn.

The Criteria That There Must Be Reasons for Combining The Kamiya et al and Bleys et al References Has Not Been Established

The first criteria of the Examiner's initial burden of factually supporting a *prima facie* conclusion of obviousness is: the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). The rejection in the Office Action mailed March 6, 2007 does not provide an explanation of how or why the Kamiya et al reference and the Bleys et al reference could be combined. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 46 and 49 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

35 U.S.C. §103(a) Rejection – Claims 48-52 Kamiya In View of Maitland

In the Office Action mailed March 6, 2007, claims 48-52 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Kamiya et al reference in view of the Maitland et al reference.

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 48-52 under 35 U.S.C. §103(a) over the Kamiya et al reference in view of the Maitland et al reference is respectfully traversed. Applicants have amended claims 48-52 and submit that the Kamiya et al reference and the Maitland et al reference do not support a 35 U.S.C. §103(a) rejection. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). To establish a *prima facie*

case of obviousness, three basic criteria must be met. First, the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). Second, there must be a reasonable expectation of success. Third, the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in *Graham v. John Deere Co.* is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: "the scope and content of the prior art," ascertaining "the differences between the prior art and the claims at issue," and resolving "the level of ordinary skill in the pertinent art."

The Criteria That The Kamiya et al and Maitland et al References Must Teach All Claim Limitations Has Not Been Established

Applicants point out that the many elements of Applicants' amended claims 48-52 are not found in the Kamiya et al reference or the Maitland et al reference. For example, the following elements of Applicants' claims 48-52 are not found in the Kamiya et al reference or the Maitland et al reference:

"providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

"positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly when said shape memory polymer material body is in said secondary shape," or

“causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly,” or

“wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises delivering electromagnetic energy optically to said shape memory polymer material body comprising a shape memory polymer foam,” or

“wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using a collapsed shape memory polymer foam device connected at the end of a guide wire,” or

“wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using a collapsed shape memory polymer foam device connected at the end of a guide wire,” or

“wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises optical heating said shape memory polymer material body comprising a shape memory polymer foam through optic fibers,” or

“wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using a laser and an optical fiber to transmit laser light through said optical fiber.”

Since the limitations listed and described above are not shown by either the Kamiya et al reference or the Maitland et al reference, a *prima facie* case of obviousness has not been established. Further, since both the Kamiya et al

reference and the Maitland et al reference fail to show the claim limitations of Applicants' claims 48-52, there can be no combination of the two references that would show Applicant's invention. There is no combination of Kamiya et al reference and the Maitland et al reference that would produce the combination of elements of Applicants' amended claims 48-52. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 48-52 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

The Criteria That There Must Be Reasons for Combining The Kamiya et al and Maitland et al References Has Not Been Established

The first criteria of the Examiner's initial burden of factually supporting a *prima facie* conclusion of obviousness is: the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). The rejection in the Office Action mailed March 6, 2007 does not provide an explanation of how or why the Kamiya et al reference and the Maitland et al reference could be combined. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 48-52 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

35 USC §103(a) Rejection – Claims 53-56 Kamiya In View Porter

In the Office Action mailed March 6, 2007, claims 53-56 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Kamiya et al reference in view of the Porter reference.

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 53-56 under 35 U.S.C. §103(a) over the Kamiya et al reference in view of the Porter reference is respectfully traversed. Applicants have amended claims 53-56 and submit that the Kamiya et al reference and the

Porter reference do not support a 35 U.S.C. §103(a) rejection. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). Second, there must be a reasonable expectation of success. Third, the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in *Graham v. John Deere Co.* is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: "the scope and content of the prior art," ascertaining "the differences between the prior art and the claims at issue," and resolving "the level of ordinary skill in the pertinent art."

The Criteria That The Kamiya et al and Porter References Must Teach All Claim Limitations Has Not Been Established

Applicants point out that the many elements of Applicants' amended claims 53-56 are not found in the Kamiya et al reference or the Porter reference. For example, the following elements of Applicants' claims 53-56 are not found in the Kamiya et al reference or the Porter reference:

"providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly," or

"positioning said shape memory polymer material body comprising a shape memory polymer foam in the interior of the physical anomaly

when said shape memory polymer material body is in said secondary shape,” or

“causing said shape memory polymer material body comprising a shape memory polymer foam to change to said larger primary shape for occluding the anomaly,” or

“wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using microparticles that convert RF radiation to heat,” or

“wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using microparticles of a material which can selectively absorb RF radiation converting it to heat,” or

“wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using microparticles of a material which can selectively absorb RF radiation converting it to heat,” or

“wherein said step of providing a shape memory polymer material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of the physical anomaly and a larger primary shape for occluding the anomaly comprises using nanoparticles of a material which can selectively absorb RF radiation converting it to heat.”

Since the limitations listed and described above are not shown by either the Kamiya et al reference or the Porter reference, a *prima facie* case of obviousness has not been established. Further, since both the Kamiya et al reference and the Porter reference fail to show the claim limitations of Applicants’ claims 53-56, there can be no combination of the two references that would show Applicant’s invention. There is no combination of Kamiya et al

reference and the Porter reference that would produce the combination of elements of Applicants' amended claims 53-56. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 53-56 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

The Criteria That There Must Be Reasons for Combining The Kamiya et al and Porter References Has Not Been Established

The first criteria of the Examiner's initial burden of factually supporting a *prima facie* conclusion of obviousness is: the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). The rejection in the Office Action mailed March 6, 2007 does not provide an explanation of how or why the Kamiya et al reference and the Porter reference could be combined. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 53-56 under 35 USC 103(a), and the rejection should be withdrawn.

35 USC §103(a) Rejection – Claims 4 and 26 Kamiya et al or Maitland et al

In the Office Action mailed March 6, 2007, claims 4 and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Kamiya et al reference or Maitland et al reference.

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 4 and 26 under 35 U.S.C. §103(a) over the Kamiya et al reference or Maitland et al reference is respectfully traversed. Applicants have amended claims 4 and 26 and submit that the Kamiya et al reference and the Maitland et al reference do not support a 35 U.S.C. §103(a) rejection. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion

of obviousness (M.P.E.P. Section 2142). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). Second, there must be a reasonable expectation of success. Third, the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in *Graham v. John Deere Co.* is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: "the scope and content of the prior art," ascertaining "the differences between the prior art and the claims at issue," and resolving "the level of ordinary skill in the pertinent art."

The Criteria That The Kamiya et al and Maitland et al References Must Teach All Claim Limitations Has Not Been Established

Applicants point out that the many elements of Applicants' amended claims 4 and 26 are not found in the Kamiya et al reference or the Maitland et al reference. For example, the following elements of Applicants' claims 4 and 26 are not found in the Kamiya et al reference or the Maitland et al reference:

"a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam," or

"a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly," or

"a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for

occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly,” or

“wherein said shape memory foam is a shape memory polymer foam composed of a polyurethane shape memory polymer with an open cell foam structure,” or

“wherein said shape memory polymer material body that comprises a shape memory polymer foam is a shape memory polymer foam with an open cell foam structure including a light absorbing dye.”

Since the limitations listed and described above are not shown by either the Kamiya et al reference or the Maitland et al reference, a *prima facie* case of obviousness has not been established. Further, since both the Kamiya et al reference and the Maitland et al reference fail to show the claim limitations of Applicants’ claims 4 and 26, there can be no combination of the two references that would show Applicant’s invention. There is no combination of Kamiya et al reference and the Maitland et al reference that would produce the combination of elements of Applicants’ amended claims 4 and 26. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 4 and 26 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

The Criteria That There Must Be Reasons for Combining The Kamiya et al and Maitland et al References Has Not Been Established

The first criteria of the Examiner’s initial burden of factually supporting a *prima facie* conclusion of obviousness is: the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int’l. Co. v. Teleflex, Inc.). The rejection in the Office Action mailed March 6, 2007 does not provide an explanation of how or why the Kamiya et al reference and the Maitland et al reference could be combined. Thus, the combination of references in the Office Action mailed March

6, 2007 fails to support a rejection of claims 4 and 26 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

35 USC §103(a) Rejection – Claims 16 and 38 Maitland et al

In the Office Action mailed March 6, 2007, claims 16 and 38 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Maitland et al reference.

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 16 and 38 under 35 U.S.C. §103(a) over the Maitland et al reference is respectfully traversed. Applicants have amended claims 16 and 38 and submit that the Maitland et al reference does not support a 35 U.S.C. §103(a) rejection. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the Examiner must provide reasons for combining the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc.). Second, there must be a reasonable expectation of success. Third, the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in *Graham v. John Deere Co.* is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: "the scope and content of the prior art," ascertaining "the differences between the prior art and the claims at issue," and resolving "the level of ordinary skill in the pertinent art."

The Criteria That The Maitland et al Reference Must Teach All Claim Limitations Has Not Been Established

Applicants point out that the many elements of Applicants' amended claims 16 and 38 are not found in the Maitland et al reference. For example, the following elements of Applicants' claims 16 and 38 are not found in the Maitland et al reference:

"a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam," or

"a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly," or

"a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly," or

"wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing dye in an elastomeric coating on said shape memory material body that comprises a shape memory polymer foam," or

"shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam," or

"a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism," or

"an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in interior of the aneurism," or

"wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam

with a primary shape and a secondary shape comprises a light absorbing dye in an elastomeric coating on said shape memory material body that comprises a shape memory polymer foam.”

Since the limitations listed and described above are not shown by the Maitland et al reference, a *prima facie* case of obviousness has not been established. Further, since the Maitland et al reference fails to show the claim limitations of Applicants’ claims 16 and 38, there can be no modification of the reference that would produce the combination of elements of Applicants’ amended claims 16 and 38. Thus, the combination of references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 16 and 38 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

The Criteria That There Must Be Reasons for Modifying the Reference Has Not Been Established

The first criteria of the Examiner’s initial burden of factually supporting a *prima facie* conclusion of obviousness is: the Examiner must provide reasons for combining or modifying the references (Margaret A. Focarino May 3, 2007 Memorandum Re: Supreme Court decision on KSR Int’l. Co. v. Teleflex, Inc.). The rejection in the Office Action mailed March 6, 2007 does not provide an explanation of how or why the reference could be combined. Thus, the references in the Office Action mailed March 6, 2007 fails to support a rejection of claims 16 and 38 under 35 U.S.C. §103(a), and the rejection should be withdrawn.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated March 6, 2007 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



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